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Docket No.: 1056-0125P  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Shigeki HIBI et al.

Application No.: 10/689,088

Confirmation No.: 6122

Filed: October 21, 2003

Art Unit: 1625

For: 7-PHENYLPYRAZOLOPYRIDINE  
COMPOUNDS

Examiner: E. M. Huang

**LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

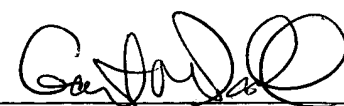
Sir:

Attached hereto is an English translation of the International Preliminary Examination Report (Form PCT/IPEA/409) for the corresponding PCT Application that should be made of record in the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: October 20, 2005

Respectfully submitted,

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for  
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Attachment(s)

Translation

PATENT COOPERATION TREATY

PCT/JP2003/013490



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

|   |  |  |
|---|--|--|
| Applicant's or agent's file reference<br>FP02-0267-00   | FOR FURTHER ACTION<br>See Form PCT/IPEA/416                                |  |
| International application No.<br>PCT/JP2003/013490  | International filing date (day/month/year)<br>22 October 2003 (22.10.2003) | Priority date (day/month/year)<br>22 October 2002 (22.10.2002) |
| International Patent Classification (IPC) or national classification and IPC<br>C07D 471/04, A61K 31/437, 31/4545, 31/5377, 31/695, A61P 1/00, 1/04, 1/08, 1/10, 1/12, 5/38, 25/00, 25/18, 25/20, 25/22, 25/24, C07F 7/18 |  |  |
| Applicant<br>EISAI CO., LTD.  |  |  |

|  |
|--|
| 1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.   |
| 2. This REPORT consists of a total of <u>10</u> sheets, including this cover sheet.  |
| 3. This report is also accompanied by ANNEXES, comprising: <ul style="list-style-type: none"> <li>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:             <ul style="list-style-type: none"> <li><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</li> <li><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</li> </ul> </li> <li>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</li> </ul> |
| 4. This report contains indications relating to the following items: <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Box No. I Basis of the report</li> <li><input type="checkbox"/> Box No. II Priority</li> <li><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li><input type="checkbox"/> Box No. IV Lack of unity of invention</li> <li><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li><input checked="" type="checkbox"/> Box No. VI Certain documents cited</li> <li><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</li> <li><input type="checkbox"/> Box No. VIII Certain observations on the international application</li> </ul>   |

|  |   |
|--|---|
| Date of submission of the demand<br>27 January 2004 (27.01.2004) | Date of completion of this report<br>19 May 2004 (19.05.2004) |
| Name and mailing address of the IPEA/JP                          | Authorized officer  |
| Facsimile No.  | Telephone No.   |

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/013490

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:

- ☐ international search (under Rules 12.3 and 23.1(b))  
☐ publication of the international application (under Rule 12.4)  
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ the claims:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ the drawings:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## Supplemental Box Relating to Sequence Listing

## Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:
  - a. type of material
    - ☒ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material
    - ☒ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing
    - ☒ contained in the international application as filed
    - ☐ filed together with the international application in computer readable form
    - ☐ furnished subsequently to this Authority for the purpose of search and/or examination
    - ☐ received by this Authority as an amendment\* on \_\_\_\_\_
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

*\* If item 4 in Box No. 1 applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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## Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 20-22

because:

☒ the said international application, or the said claims Nos. 20-22  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See supplemental sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 20-22

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the  
Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with  
the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ see Supplemental Box for further details.

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III. 1.

Claims 20-22 pertain to methods for treatment of  
the human body by therapy.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

|                               |        |                    |     |
|-------------------------------|--------|--------------------|-----|
| Novelty (N)                   | Claims | 1-11, 15-19, 23-24 | YES |
|                               | Claims | 12-14              | NO  |
| Inventive step (IS)           | Claims | 1-11, 15-19, 23-24 | YES |
|                               | Claims | 12-14              | NO  |
| Industrial applicability (IA) | Claims | 1-19, 23-24        | YES |
|                               | Claims |                    | NO  |

## 2. Citations and explanations

Document 1: WO 02/18320 A12 (Tanabe Seiyaku Co., Ltd.),  
25 September 2002

See compounds of general formula [X] (page 23: in  
this general formula Q is -CH<sub>2</sub>-)

Document 2: JP 2001-89368 A (Tanabe Seiyaku Co., Ltd.), 3  
April 2001

Discloses 2,6-dimethoxy-4-[(t-butyl-diphenylsilyl-  
oxy)methyl]benzeneboric acid (page 58, paragraph [0288]),  
2,6-dimethoxy-4-(2-hydroxyethyl)benzeneboric acid (page  
60, paragraph [0300]) and 2,6-dimethoxy-3-(hydroxymethyl)-  
benzeneboric acid (page 67, paragraph [0334])

Claims 12-14

The inventions set forth in claims 12-14 are not  
novel and do not involve an inventive step in the light of  
documents 1 and 2, cited in the international search  
report.

Documents 1 and 2 disclose compounds which fall  
within the scope of compounds represented by the general  
formula presented in claim 12 in the present international  
application.

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

International application No.

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Claims 1-11, 15-19 and 23-24

The inventions set forth in claims 1-11, 15-19 and 23-24 are novel and involve an inventive step relative to documents 1 and 2.

Given that claims 1-11 in the present international application set forth inventions relating to compounds represented by general formula (I) and claims 15-19 and 23-24 in this application set forth inventions relating to medicaments using a compound represented by general formula (I), documents 1 and 2 do not disclose or suggest such inventions.



# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/013490

## Box No. VI Certain documents cited

### 1. Certain published documents (Rule 70.10)

Application No.  
Patent No.

Publication date  
(day/month/year)

Filing date  
(day/month/year)

Priority date (valid claim)  
(day/month/year)

See supplemental sheet

### 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure  
(day/month/year)

Date of written disclosure  
referring to non-written disclosure  
(day/month/year)

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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## Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: VI. 1.

WO 03/078435 A1      25.09.2003      11.03.2003      13.03.2003  
(Pharmacia & Upjohn Co.)

EX

WO 02/088121      07.11.2002      25.04.2002      27.04.2001  
(Eisai Co., Ltd.)

EX

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

In claim 24, "use of a compound described in claim 1 or a salt thereof or a hydrate thereof for a therapeutic agent or prophylactic agent for a disorder wherein a corticotrophin ... is efficacious" appears to be an error for "use of a compound described in claim 1 or a salt thereof or a hydrate thereof for producing a therapeutic agent or prophylactic agent for a disorder wherein a corticotrophin ... is efficacious".